

510(k) Summary

Submitter: Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Date Prepared: July 15, 2004

Contact: Kristin Jans
Manager, Regulatory Affairs

Proprietary Name: ST360™ Spinal Fixation System

Common Name: Rod, hook, and screw spinal instrumentation

**Device Product Code
& Classification:** Class III; MNI, MNH, KWP, NKB

Predicate Device: ST360™ Spinal Fixation System (formerly Cadence)
(K022374)

Device Description:

The ST360™ Spinal Fixation System is a temporary implant system used to correct spinal deformity and to facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar, and sacral areas of the spine. Implants in this system consist of hooks and/or screws connected to rods that are intended to be removed after solid fusion has occurred. The system includes polyaxial screws of varying diameters and lengths; fixed screws of varying diameters and lengths; rods in varying lengths; hooks in varying designs; and transverse connectors in the various configurations of fixed, adjustable, variable angle offset and axial. All implant components are either top loading and top tightening. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F-136.

Intended Use:

The ST360™ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities (i.e., scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

Statement of Technological Comparison:

Mechanical testing was carried out according to ASTM F 1717 and ASTM F 1798 to validate the modifications to the ST360™ Spinal Fixation System. The testing demonstrated substantially equivalent mechanical properties to the previously cleared Silhouette™ Spinal Fixation System and ST360™ Spinal Fixation System components.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2008

Zimmer Spine, Inc.
c/o Mr. Tim Crabtree
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, MN 55439

Re: K041925

Trade/Device Name: ST360™ Spinal Fixation System
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminar fixation orthosis; pedicle screw spinal system
Regulatory Class: Class III
Product Code: KWP, MNH, MNI, NKB
Dated: September 24, 2004
Received: September 24, 2004

Dear Mr. Crabtree:

This letter corrects our substantially equivalent letter of September 24, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K041925

Device Name: *ST360*® Spinal Fixation System

Indications for Use:

The *ST360*° Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

When used as a hook and sacral screw system, the *ST360* Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined as chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic, deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the *ST360*° Spinal Fixation System are intended for the sacral iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

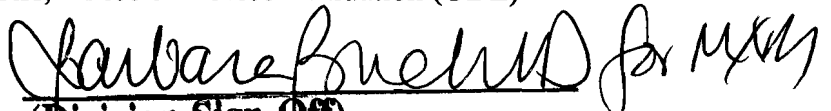
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

ST360 Spinal Fixation System K041925

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 K041925

510(k) Summary

Submitter: Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

Date Prepared: August 30, 2007

Contact: Tim Crabtree
Senior Regulatory Affairs Specialist

Device Name: Trade Name: *ST360°*® Spinal Fixation System
Common Name: Rod, hook, and screw spinal instrumentation

Classification: Class III

Product Codes: NKB, MNI, MNH, KWP

Predicate Device: *ST360°*® Spinal Fixation System (K022374, K041925)

Device Description:

The *ST360°*® Spinal Fixation System is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of hooks and/or screws connected to rods and are intended to be removed after solid fusion has occurred. This system includes polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rods in varying lengths, hooks in varying designs, fixed and adjustable transverse connectors. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V), conforming to ASTM F-136.

Intended Use:

The *ST360°* Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

When used as a hook and sacral screw system, the *ST360* Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined as chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic, deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the *ST360°* Spinal Fixation System are intended for the sacral iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

Statement of Technological Comparison:

There are no changes to the material of construction or the mechanism of action to the *ST360°* Spinal Fixation System. The modified system has the same fundamental scientific technology and intended use and indications as the predicate device.